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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,277	GUDAS ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 41, 44 in part, 18, 49-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 41, 44 in part, 18, 49-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10.11.05; 9.7.04; 11.10.03*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XV, claims 1, 2, 41 and 44 in part and 18 in the reply filed on 12/02/2005 is acknowledged. The traversal is on the ground(s) that the claims of Groups I-XXXVII, i.e. Claims 1-41 and 44, are drawn to human monoclonal antibodies that binds to MCP-I, and thus, contrary to the Examiner's assertions regarding binding to a variety of distinct epitopes, there is an intimate connection between the claimed products in that they all comprise human monoclonal antibodies that binds to MCP-I. This is not found persuasive because restriction requirements are set forth for reasons of patentable distinction between each independent invention so as to warrant separate classification and search. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from the other or independent from the other. The inventions of Groups I-XXXVII are distinct, each from the other, because each is a different antibody that comprises a distinct light chain and a distinct heavy chain, each of which comprise an amino acid sequence that differs from those of light and heavy chains of the other antibodies. As such, the search required to examine any one of the inventions of Groups I-XXXVII is different from the search required to examine any of the others. Moreover, the search necessary to examine claims directed to any of the inventions of Groups I-XXXVII is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Furthermore, the

search necessary to examine claims directed to any one of the inventions is not required to examine any of the others, nor would it be meaningful to the examination of claims directed to any of the others. Since the inventions of Groups I-XXXVII are patentably distinct, each from the others, and because the examination of more than one of the inventions could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803. For example, Stancoviski et al. *(Proceedings of the National Academy of Science USA.* 1991; 88: 8691-8695) characterized the binding effects upon the growth of tumor cells of different antibodies, each of which bind different epitopes of the extracellular domain of a tumor-associated antigen related to EGFR, namely ErbB2; see entire document (e.g., the abstract). Stancovski et al. teaches some anti-ErbB2 antibodies inhibited tumor cell growth, but others actually accelerated their growth (page 8693, column 1). By way of explanation, Jiang et al. (*J. Biol. Chem.* 2005 Feb 11; 280 (6): 4656-4662) teaches that it is well known that different biological effects are associated with epitope specificity of the antibodies; see entire document, particularly page 4656, column 2. Reimer et al. (*Mol. Immunol.* 2005; 42: 1121-1124) teaches, because antibodies binding the same antigens have been shown to both ameliorate and aggravate disease symptoms, the concept of epitope specificity, as opposed to mere antigen specificity, in humoral immunology has gained importance in modern medicine; see entire document, particularly page 1123, column 1. In addition, Reimer et al. (*J. Immunol.* 2004; 173: 394-401) also teaches the diverse biological effects that are exerted by different anti-HER2 antibodies depends upon epitope specificity; see entire document (e.g., the abstract). Further, the different groups require

different search terms and different search strategies which create a burden on the examiner. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-17, 19-40, 42, 43 and 45-48 are withdrawn from further consideration under 37 C.F.R. 1.142(b) as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply on 03/14/05.

3. Claims 1, 2, 41, 44 in part, 18 and the newly added claims 49-52 read on the elected invention, and are examined on merits.

4. It is noted that claim 51 consists of the amino acid sequence "ISVQRLASYRRITSSK" without any reference to the SEQ ID NO it corresponds to. It is indicated as a peptide having the amino acid sequence from residues 20-35 of SEQ ID NO:149, and this information was used for STIC sequence search purposes. However, by merely listing the amino acid sequence and not the corresponding SEQ ID NO in the claim is improper and, hence the applicant is requested to assign an appropriate SEQ ID NO for the sequence and incorporate it into the claim language.

Claim Objections

5. Claims 1 and 2 are objected to because of the following informalities: the claims consist of non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. It has been noted that the applicant did not provide the information pertaining to the deposit of the claimed monoclonal antibodies 3.11.01 or 3.11.2.

Claims 49, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the monoclonal antibodies 3.11.1 or 3.11.2. It is not clear that the monoclonal antibodies 3.11.1 or 3.11.2 are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of an antibody is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed monoclonal antibodies, this method will not necessarily reproduce antibodies which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive a chimeric monoclonal antibody identical to those claimed. Undue experimentation would be required to screen all of the possible antibody species to obtain the claimed antibodies.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed monoclonal antibodies 3.11.1 or 3.11.2, a suitable deposit is required for patent purposes, evidence of public availability of the claimed monoclonal antibodies 3.11.1 or 3.11.2 or evidence of the reproducibility without undue experimentation of the claimed monoclonal antibodies 3.11.1 or 3.11.2, is required.

Applicant's failure to refer to the deposit information pertaining to the monoclonal antibodies 3.11.1 or 3.11.2 in the specification is noted and it is required that the required deposit be made and all the conditions of 37 CFR 1.801-1.809 met.

If the deposit of the monoclonal antibodies 3.11.1 or 3.11.2 is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit of the monoclonal antibodies 3.11.1 or 3.11.2 has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit of the monoclonal antibodies 3.11.1 or 3.11.2 is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of

deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same

as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Conclusion

14. No claims are allowed

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER